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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/805,813	02/26/1997	ICHIRO MITSUHARA	085760-000	2736

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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 02/25/2003

44

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/805,813

Applicant(s)

MITSUHARA ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48,49,52-59 and 62-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48,49,52-59 and 62-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The cancellation of claims 50-51 and 60-61 and the amendment of claims 48-49, 52-54, 56, 58, 62-63, 65 and 67 requested in Paper No. 43, filed 11 December, 2002, have been entered. Claims 48-49, 52-59 and 62-67 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from the Brief Description of Figures 2-5.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth below. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Response to Amendment

4. The objection to claim 49 because of informalities is obviated by amendment.

5. The rejection of claims 48-67 are rejected under 35 U.S.C. 112, first paragraph, as containing new matter is WITHDRAWN in light of amendment of the claims to remove reference to "sarcotoxin 1 family", "cecropin family" or "cecropin A".

6. The rejection of claims 48-67 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention IS WITHDRAWN in light of amendment of the claims to limit the invention to use of a sarcotoxin 1a gene.

Claim Rejections - 35 USC § 112

7. Claims 48-49, 52-59 and 62-67 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of conferring on a plant resistance to pathogenic fungi by transformation with an expression cassette encoding a fusion protein comprising the PR-1a signal peptide and sarcotoxin 1a or one comprising the PR-1a signal peptide, sarcotoxin 1a, the hinge region of tobacco chitinase and the mature PR-1a operably linked to a dual promoter comprising an inducible promoter and a constitutive promoter, and plants so transformed, does not reasonably provide enablement for a method of conferring on a plant resistance to pathogenic fungi by transformation with any expression cassette encoding sarcotoxin 1a operably linked to a dual promoter comprising an inducible promoter and a constitutive promoter, and plants so transformed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 June 2002, as applied to claims 48-67. Applicant's arguments filed 11 December 2002, have been fully considered but they are not persuasive.

Applicant urges that the specification teaches how to make vectors in which the sarcotoxin 1a gene is fused to a signal sequence and how to make vectors in which the sarcotoxin

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1a gene is not so fused. Applicant urges that Example 4 teaches that transformants were obtained that express the non-fusion gene, and examples 8-10 and Tables 1 and 2 and Figure 15 teach that those plants are resistant to three pathogens. With respect to Okamoto et al, Applicant urges that the instant specification teaches that plants transformed with a nucleic acid encoding a signal sequence fused or not fused to sarcotoxin 1a are resistant to 3 pathogens. Applicant urges that one of the constructs taught by Okamoto et al is similar to the Pr-1a signal sequence-sarcotoxin 1a construct taught in the instant specification; the only difference is the promoter used; Applicant thus urges that Okamoto et al support the enablement of the instant specification. Applicant also urges that the other constructs taught by Okamoto et al fall outside the scope of the claimed invention - the instant invention is limited to fusion with a plant gene, not a bacterial gene, and Okamoto et al used a different linker between the peptides. Applicant urges that there was no evidence presented in the prior Office action that producing pathogen resistant plants by transformation with a sarcotoxin/plant gene fused via the tobacco chitinase hinge is unpredictable. Applicant urges that the Examiner has the burden to show why any promoter induced by stress and why any signal sequence cannot be used in the claimed invention, and that it would be routine experimentation to use other such sequences (response pg 5-11)

This is not found persuasive. Example 4 describes the detection of the fusion protein in transformed plants (see for example, pg 24, line 12, and pg 254, line 5); the example does not discuss the detection of non-fusion protein. Examples 8-10, Tables 1 and 2 and Figure 15 are drawn to resistance of tobacco transformed with the fusion gene (see pg 29, line 29, and pg 31, line 9); PSP and PSS are fusion constructs in which the PR-1a signal sequence is fused to

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sarcotoxin 1a (see Figure 8). Thus, the specification does not teach that plants transformed with the non-fusion protein are resistant to pathogens, but instead teaches that the signal sequence is required.

The specification does not teach any other plant genes that can be used in the fusion constructs, and teaches that PR-1a must be used (pg 2, lines 18-22):

since a short peptide such as Sarcotoxin 1a is expected to be unstable in plants, it is necessary to stabilize the peptide by producing it as a fusion protein with PR-1a which is an [*sic*] pathogenesis related protein of tobacco.

The specification also does not teach any stress-induced promoters known at the time of filing other than the PR-1a promoter.

Okamoto et al teach the unpredictability of the expression of sarcotoxin fusion constructs. Okamoto et al teach that while GUS can be expressed very well in the transgenic plants (see Fig. 2), the expression of the attached sarcotoxin and the resulting resistance of the plants depended on the configuration of the construct (see pg 61, right column, paragraph 2). There is no reason to suspect that any random plant gene in the place of GUS would produce different results. The only constructs shown to work in the instant specification are PSP and PSS, which are Pr-1a signal-sarcotoxin and Pr-1a signal-sarcotoxin-chitinase hinge-PR-1a protein constructs. Again it is noted that the specification states that presence of Pr-1a protein in the construct is required.

8. Claims 48-49 and 52-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claim 48 lacks antecedent basis for the limitation "the transformed plant cell" in line 9.

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9. Claims 48-67 are free of the prior art, given the failure of the prior art to teach or suggest a method of conferring on a plant resistance to pathogenic fungi by transformation with an expression cassette encoding sarcotoxin 1a operably linked to a dual promoter comprising an inducible promoter and a constitutive promoter, and plants thereby obtained.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
February 19, 2003



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